UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419

20999 7590 07/05/2007

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,042	BARROWCLIFFE, TREVOR	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *9-12,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 13-15, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The FINALITY of the previous office action is withdrawn and this office action is non-final

This office action is in response to the paper filed on 6/11/2007.

Status of Claims

Claims 1-18 are pending. Claims 1-8, 13-15, and 18 are currently pending and under consideration. Claims 9-12 and 16-17 are withdrawn.

Rejections Withdrawn

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention, is withdrawn because the Applicants amended claim 1 to a "kit" comprising two compositions.

Rejection Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13-15, and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (U.S. 5,506,112).

Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a sample containing factor VIII, thus activating factor VIII to be assayed; and

where subsequently activated factor VIII forms complex with factor IXa. See column 1, lines 8-14.

Applicants stated that Lang does not teach, or even suggest, a kit comprising pharmaceutical compositions (claims 1-3), a method comprising mixing together coagulation factors VIII and IX into a pharmaceutical composition (claims 13-15) or the pharmaceutical composition as described in claim 18.

Examiner responds that amending the claims to refer to a kit does not overcome the rejection over Lang because *In re Haller,* 73 USPQ 403 (CCPA 1946), the Court held that an old compound, packaged and labeled to show its use, is not patentable. Therefore, the new claim limitation of a "kit" does not overcome the rejection over Lang.

Claims 4-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al. (U.S. 4,965,199).

Capon et al. teach a method for producing factor VIII in recombinant mammalian host cell. See Abstract. Figure 1 teaches a step where factor IXa initiates the conversion of factor X to the activated form, factor Xa; where factor VIII is currently believed to function as a cofactor and is required to enhance the activity of factor IXa. This step in a cascade is critical, since two most common hemophilia disorders have been determined to be caused by the decreased functioning of either factor VIII (hemophilia A or classic hemophilia) or factor IXa (hemophilia B).

Therefore, factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa as well as correcting the coagulation defect in plasma derived

from hemophilia A affected individuals. See column 10, lines 27-32. Claim 8 is included in this rejection because it depends from rejected independent base claim 4.

Applicants state that the claims as currently presented refer to a method of treating haemophilia A or B that comprises administering to a patient the claimed composition. Also, Applicants argue that Capon is directed to a method for producing factor VIII in recombinant mammalian host cells, and does not teach or suggest the administration of a pharmaceutical composition consisting essentially of coagulation factors VIII and IX to a patient.

Examiner responds that Capon teaches that factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa, as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals. See column 10, lines 27-32. Also, as Figure 1 of Capon shows, the surface-mediated activation of blood coagulation, where factor IXa initiates the conversion of factor X to the activated form, and where factor VIII is currently believed to function as a cofactor and is required to enhance the activity of factor IXa. This activation pathway is critical, since two most common hemophilia disorders have been determined to be caused by the decreased functioning of either factor VIII (hemophilia A or classic hemophilia) or factor IXa (hemophilia B).

Further, Applicants state that Figure 1 of Capon does not show the decrease in concentration of factor VIII in the composition due to the presence of factor IXa.

Examiner responds that factor VIII and factor IXa both take part in the cascade reaction of surface mediated activation of blood coagulation, as depicted in Figure 1(I) and their concentrations will relate to each other as articulated in the instant claim 4, where it states: "*wherein in the presence of coagulation factor IXa allows the concentration of coagulation factor VIII in the composition to be reduced in comparison to a composition which does not comprise a coagulation factor IXa.*"

Therefore, the rejection stands.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER